

REMARKS

Claims 1-4, 7, 19, 20, 22, 23, 25, 29-32 and 35 are currently amended. Amendments are made to the claims to more clearly set forth the claimed subject matter and to place the claims in condition for allowance. Applicants do not believe the amendments change the scope of the claims. Claims 1-57 remain pending. Reconsideration of the application in view of the current claims is respectfully requested and further in view of the following Remarks.

I. OBJECTIONS TO THE SPECIFICATION

The Examiner has requested a new Abstract. Applicants have provided a new Abstract. Therefore, Applicants request that the Examiner withdraw the objection.

II. INFORMATION DISCLOSURE STATEMENT

Applicants acknowledge, with appreciation, the Examiner's indication that the references submitted in the Information Disclosure Statement filed December 5, 2001 have been considered. Applicants submit in a separate communication a Supplemental Information Disclosure Statement by Express Mail along with the required fee.

III. CLAIM REJECTIONS UNDER 35 U.S.C. §102(E)

In order for Applicants' claims to lack novelty under 35 U.S.C. § 102 (*i.e.*, be anticipated), each and every element of the claimed invention must be disclosed in a single prior art reference. A prior art reference anticipates a claim *only if* the reference discloses, either expressly or inherently, every limitation of the claim. The Patent Examiner bears the burden of demonstrating that Applicants' invention is anticipated by the reference relied on in the Examiner's reasons for rejection.

For the following reasons, Applicants believe the Examiner has not met this burden.

i. Claim 20-22, 26-35

The Examiner rejected claims 20-22, and 26-35 under 35 U.S.C. §102(e) as being unpatentable in view of Sparks (U.S. Pat. Publication No. **2001/0037215**).

The Examiner asserts that:

as per claim 20, Sparks discloses a method for collecting data (Sparks; paragraph 3), comprising: (a) providing a medical test to a patient (Sparks; paragraph 33); (b) collecting the testing apparatus from the user once the user completes testing (Sparks; paragraph 37); and

(c) distributing test information from the apparatus to authorized recipients (Sparks; paragraph 38).

Applicants' independent claim 20, as amended, is directed to a method for collecting data. The method comprises the steps of providing a testing apparatus to a patient in response to a request for the testing apparatus; administering a medical test to the patient with the testing apparatus; collecting the testing apparatus from the patient once the patient completes testing; and distributing test information from the testing apparatus to authorized recipients.

Sparks '215 discloses "an almost effortless way by which physicians and other medical subscribers to the System 5 can make education recommendations or 'Educational Prescriptions' to their patients and accomplish the goal of integrating the education into the patient's treatment plan." (see, column 5, paragraph [0043]). Nothing in Sparks discloses providing a testing apparatus to a patient in response to a request for the testing apparatus; administering a medical test to the patient with the testing apparatus; collecting the testing apparatus from the patient once the patient completes testing; and distributing test information from the testing apparatus to authorized recipients as claimed by Applicants.

For the foregoing reasons, Applicants' claim 20 is not anticipated by Sparks '215 under 35 U.S.C. § 102(e). Therefore, Applicants request that the Examiner withdraw the rejection of claim 20. Furthermore, claims 21, 22, and 26-35 depend directly or indirectly from claim 20 and include the limitations thereof. For the reasons provided with respect to claim 20, claims 21, 22 and 26-35 are not anticipated by Sparks under 35 U.S.C. § 102(e). Therefore, Applicants also request that the rejection of claims 21, 22 and 26-35 under 35 U.S.C. § 102(e) be withdrawn as well.

ii. Claim 37-40

The Examiner rejected claims 37-40 under 35 U.S.C. §102(e) as being unpatentable in view of Sparks (U.S. Pat. Publication No. **2001/0037215**).

The Examiner asserts, with respect to claim 37 (which depends from claim 36), that "Sparks discloses the method of claim 36 wherein said steps are performed sequentially (Sparks; paragraph 87)."

Applicants' independent Claim 36 is directed to a method for conducting a medical test for an authorized physician. The steps of the method include (a) collecting an order for a device;

(b) transmitting a medical test device to a user; (c) extracting test results from the test device; (d) retrieving the test device from the user subsequent to the user inputting test results into the device; and (e) distributing test results to authorized recipients.

The Examiner has not asserted that Applicants' independent claim 36 is anticipated by Sparks. Thus, each of the claim limitations of claim 36 are not disclosed in Sparks. Claims 37-40 depend directly or indirectly from claim 36 and include the limitations thereof. Since the Examiner has provided no indication that claim 36 is anticipated by Sparks, claims 37-40 cannot be anticipated by Sparks under 35 U.S.C. § 102(e). Therefore, Applicants request that the rejection of claims 37-40 under 35 U.S.C. § 102(e) be withdrawn.

iii. Claims 42-50

The Examiner rejected claims 42-50 under 35 U.S.C. §102(e) as being unpatentable over Sparks (U.S. Pat. Publication No. **2001/0037215**).

The Examiner has not asserted that independent claim 41 is anticipated by Sparks. Thus, each of the claim limitations of claim 41 are not disclosed in Sparks. Claims 42-50 depend directly or indirectly from claim 41 and include the limitations thereof. Since the Examiner has provided no indication that claim 41 is anticipated by Sparks, claims 42-50 cannot be anticipated by Sparks under 35 U.S.C. § 102(e). Therefore, Applicants request that the rejection of claims 42-50 under 35 U.S.C. § 102(e) be withdrawn.

iv. Claims 52-57

The Examiner rejected claims 52-57 under 35 U.S.C. §102(e) as being unpatentable over Sparks (U.S. Pat. Publication No. **2001/0037215**).

The Examiner has not asserted that independent claim 51 is anticipated by Sparks. Thus, each of the claim limitations of claim 51 are not disclosed in Sparks. Claims 52-57 depend directly from claim 51 and include the limitations thereof. Since the Examiner has provided no indication that claim 51 is anticipated by Sparks, claims 52-57 cannot be anticipated by Sparks under 35 U.S.C. § 102(e). Therefore, Applicants request that the rejection of claims 52-57 under 35 U.S.C. § 102(e) be withdrawn.

IV. Claim Rejections Under 35 U.S.C. §103(A)

During patent examination the PTO bears the initial burden of supporting a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, it is necessary for the Examiner to present evidence, preferably in the form of some teaching, suggestion, incentive or inference in the applied prior art, or in the form of generally available knowledge, that one having ordinary skill in the art would have been led to combine the relevant teachings of the applied references in the proposed manner to arrive at the claimed invention. Mere identification in the prior art of each element is insufficient to defeat patentability of the combined subject matter. There must also be some suggestion or motivation to modify the reference or to combine reference teachings. *See* MPEP § 2142. Thus, there must be some positive, concrete evidence which gives a logical reasoning which justifies a combination of references. Further, Applicant's explanation of how the invention works does not render obvious that which is otherwise unobvious. Finally, there must be a reasonable expectation of success and the references must teach or suggest all of the claim limitations.

In practice, this requires that the Examiner explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious. Further, the factual inquiry of whether to combine references must be based on the objective evidence of record. Failure to meet that burden is a basis for the Board to overturn the obviousness rejection. The Examiner cannot simply use Applicant's teaching to show that a person of ordinary skill would have been led to the combination of references. Similarly, the Examiner cannot provide conclusory statements supporting the rejection. As the Federal Circuit has noted the motivation-suggestion-teaching requirement protects against the entry of hindsight into the obviousness analysis.

A *prima facie* case of obviousness can be rebutted if the Applicants can show that the art teaches away from the claimed invention.

Applicants believe the Examiner has not met his burden under § 103 for the following reasons:

A. Rejection of claims 23-24 under 35 U.S.C. §103(a) over Sparks in view of Snell

The Examiner rejected claims 23-24 under 35 U.S.C. §103(a) as being unpatentable over Sparks (U.S. Pat. Publication No. 2001/0037215) in view of Snell (U.S. Pat. No. 5,722,999). The Examiner asserts that

as per claim 23, Sparks discloses the method of claim 20 wherein said step (a) includes the sub-step of: providing an id number for the medical test device; and recording the id number prior to transmitting the test device to the end user. Sparks fails to expressly teach to provide and record an id number for the medical test device, per se, since it appears that Sparks is more directed to provide information and medical device to the patient. However, this feature is well known in the art, as evidenced by Snell. In particular, Snell discloses a system and method for storing and displaying historical medical data measured by an implantable medical device, wherein unique identifier code is stored in the program memory area (Snell; col. 4, lines 21-23 and 27-29 and col.7, lines 38-41).

Claims 23-24 depend from claim 20 and include the limitations thereof.

The Examiner has not asserted that Applicants' independent claim 20 is obvious over Sparks in view of Snell. Since the Examiner has provided no indication that claim 20 is obvious over Sparks in view of Snell, claims 23-24 are also not rendered obvious in view of Sparks and Snell under 35 U.S.C. § 103. Therefore, Applicants request that the rejection of claims 23-24 under 35 U.S.C. § 103 be withdrawn.

B. Rejection of claims 25, 36 and 51 under 35 U.S.C. §103(a) over Sparks in view of "Applicant's admitted prior art"

The Examiner rejected claims 25, 36 and 51 under 35 U.S.C. §103(a) as being unpatentable over Sparks (U.S. Pat. Publication No. 2001/0037215) in view of "Applicant's admitted prior art."

i. *Claim 25*

The Examiner asserts that "as per claim 25, Sparks discloses the method of claim 20 further including the step of: (d) tracking the time following completion of said step (a) and initiating step (b) within a fixed time period."

Claim 25 depends from claim 20 and include the limitations thereof.

The Examiner has not asserted that independent claim 20 is obvious in view of Sparks and "Applicant's admitted prior art." Since the Examiner has provided no indication that claim 20 is obvious in view of Sparks and "admitted prior art," claim 25 is also not rendered obvious in view of

Sparks and “admitted prior art” under 35 U.S.C. § 103. Therefore, Applicants request that the rejection of claim 25 under 35 U.S.C. § 103 be withdrawn.

ii. Claim 36

The Examiner asserts that “as per claim 36, Sparks discloses a method for conducting a medical test for an authorized physician (Sparks; paragraph 3), comprising: (a) collecting an order for a device (Sparks; paragraph 16); (b) transmitting a medical test device to a user (Sparks; paragraph 3); (c) extracting test results from the test device; (d) retrieving the test device from the user subsequent to the user inputting test results into the device; and (e) distributing test results to authorized recipients (Sparks; paragraph 38). Sparks fails to expressly teach to extract the test results from the medical device and also retrieving the test device from the user, per se, since it appears that Sparks is more directed to obtain the results from the patient. However, this feature is well known in the prior art admitted by the applicant. In particular, applicant’s prior arts U.S. Patent No’s **5,797,852** and **5,844,996** disclose devices to provide feedback to physicians following a period of in-home testing by a patient, wherein the patient carries the device to the physician, who extracts data from the device.”

As noted by the Examiner, Sparks does not teach that the test results are extracted from the medical device. Nor does Sparks teach retrieving the test device from the user as provided for in Applicants’ independent claim 36. Applicants suggest that the proposed combination of Sparks with Karakasoglu (‘582) and Enzmann (‘996) is improper. One of ordinary skill considering the system of Sparks would have no motivation whatsoever to consider, combine or modify that device based on sleep apnea screening and detecting device of Karakasoglu (‘852) or the active electronic noise suppression system of Enzmann (‘996). Moreover, even if some motivation to combine these references could be identified, such a combination would fail to render Applicants’ claim 36 obvious because any such combination would still lack any suggestion of collecting an order for a device, transmitting a medical test device to a user, extracting test results from the test device, retrieving the test device from the user subsequent to the user inputting test results into the device; and distributing test results to authorized recipients, as provided for in Applicants’ claim 36. For at least these reasons, no combination of these references can render obvious Applicants’ claim 36. Claim 36 is

therefore allowable under 35 U.S.C. § 103. As such, the rejection of claim 36 under 35 U.S.C. § 103 should be withdrawn.

iii. Claim 51

The Examiner asserts that

as per claim 51, Sparks discloses a method for conducting a medical test for an authorized physician (Sparks; paragraph 3), comprising: (a) collecting an order for a device input via a computer and received via a communications network (Sparks; paragraph 18); (b) transmitting a medical test device to a patient at a patient defined location (Sparks; abstract and paragraph 3); (c) extracting test results from the test device; (d) retrieving the test device from the patient subsequent to the user inputting test results into the device (Sparks; paragraph 37); and (e) distributing test results to authorized recipients via a secure connection to said communications network (Sparks; paragraph 38). The obviousness of modifying the teaching of Sparks to include the extracting test results from the test device (as taught by applicant's admitted prior art) is as addressed above in the rejection of claim 36, part (c) and incorporated herein.

As noted by the Examiner with respect to the rejection of claim 36, and discussed above, Sparks does not teach that the test results are extracted from the medical device. Nor does Sparks teach retrieving the test device from the user as provided for in Applicants' independent claim 51. Applicants suggest that the proposed combination of Sparks with Karakasoglu ('582) and Enzmann ('996) is improper. One of ordinary skill considering the system of Sparks would have no motivation whatsoever to consider, combine or modify that device based on sleep apnea screening and detecting device of Karakasoglu ('852) or the active electronic noise suppression system of Enzmann ('996). Moreover, even if some motivation to combine these references could be identified, such a combination would fail to render Applicants' claim 51 obvious because any such combination would still lack any suggestion of collecting an order for a device, transmitting a medical test device to a user, extracting test results from the test device, retrieving the test device from the user subsequent to the user inputting test results into the device; and distributing test results to authorized recipients, as provided for in Applicants' claim 51. For at least these reasons, no combination of these references can render obvious Applicants' claim 51. Claim 51 is therefore allowable under 35 U.S.C. § 103. As such, the rejection of claim 51 under 35 U.S.C. § 103 should be withdrawn.

C. Claim Rejections Under 35 U.S.C. §103(a) over Sparks in view of Kulkarni

The Examiner rejected claim 41 under 35 U.S.C. §103(a) as being unpatentable over Sparks (U.S. Pat. Publication No. 2001/0037215) in view of Kulkarni (U.S. Pat. Publication No. 2001/0032098).

The Examiner asserts that

as per claim 41, Sparks discloses a system for providing a test system to a patient, comprising: i. an interface server including an ordering interface coupled to a communications network accessible by a plurality of computers (Sparks; paragraph 18); ii. a database server coupled to the interface server (Sparks; paragraph 65); iii. a logistics system transmitting a medical test to a patient at the direction of a physician accessing the ordering system via the interface server and retrieving the test from the patient upon completion of the test (Sparks; paragraph 37); and iv. a data transfer system, collecting test results from the medical test and distributing results via a secure mechanism to an authorized recipient. Sparks fails to expressly teach a data transfer system, collecting test results from the medical test and distributing results via a secure mechanism to an authorized recipient, per se, since it appears that Sparks is more directed to obtain the results from the patient. However, this feature is well known in the art, as evidenced by Kulkarni. In particular, Kulkarni discloses an internet ready medical device, wherein a control box can be modified to send the readings over the internet (Kulkarni; paragraph 36).

As noted by the Examiner, Sparks does not teach a data transfer system. Nor does Sparks teach collecting test results from the medical test and distributing results via a secure mechanism to an authorized recipient as provided for in Applicants' independent claim 41. Applicants suggest that the proposed combination of Sparks with Kulkarni is improper. One of ordinary skill considering the system of Sparks would have no motivation whatsoever to consider, combine or modify that device based on the internet ready medical device of Kulkarni. Moreover, even if some motivation to combine these references could be identified, such a combination would fail to render Applicants' claim 41 obvious because any such combination would still lack any suggestion of an interface server including an ordering interface coupled to a communications network accessible by a plurality of computers; a database server coupled to the interface server; a logistics system transmitting a medical test to a patient at the direction of a physician accessing the ordering system via the interface server and retrieving the test from the patient upon completion of the test; and a data transfer system, collecting test results from the medical test and distributing results via a secure mechanism to an authorized recipient, as provided for in Applicants' claim 41. For at least these

reasons, no combination of these references can render obvious Applicants' claim 41. Claim 41 is therefore allowable under 35 U.S.C. § 103. As such, the rejection of claim 41 under 35 U.S.C. § 103 should be withdrawn.

V. CLAIM REJECTIONS UNDER 35 U.S.C. §112

The Examiner rejected claim 1 under 35 U.S.C. §112, second paragraph, "as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." The Examiner asserts that "claim 1 discloses a method for securely collecting information from a user; but the steps of claim 1 does not provide the information about how the collection is being done." The Examiner also rejected claims 2-19 for the same reasons.

Without conceding to the Examiner's characterization of the claim, Applicants have amended claim 1 to provide a method for securely collecting information from a user. The steps of the method include (a) delivering a medical test device to a patient; (b) retrieving test data from the test device after use by a patient; and (c) distributing test data to authorized recipient. How information is collection will depend upon the type of medical test device that is delivered and would be apparent to persons of skill in the art practicing the invention.

Applicants assert that claim 1 particularly points out and distinctly claims the subject matter and is therefore patentable under 35 U.S.C. § 112. Claims 2-19 depend from claim 1 and are also patentable for the same reasons. Therefore, Applicants request that the Examiner withdraw the rejection under § 112.

CONCLUSION

In light of the remarks set forth above, Applicants believe that they are entitled to a letters patent. Applicants respectfully solicit the Examiner to expedite the prosecution of this patent application to issuance. Should the Examiner have any question, the Examiner is encouraged to telephone the undersigned.


FEE AUTHORIZATION

The Commissioner is authorized to charge any additional fees that may be required, including petition fees and extension of time fees, or credit any overpayment to Deposit Account No. **23-2415** (Attorney Docket No. 13463-701.201).

Respectfully submitted,

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By: _____


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